



Dep & Ret Room #307
Attorney's Docket No.: 07508-033001

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Manfred Schmid et al.

Unit : 3737

Serial No. : 09/914,640

Examiner : Devaang Shah

Filed : August 31, 2001

Title : ACTIVE INSTRUMENT FOR DETERMINING A POSITION IN NAVIGATION
SYSTEMS FOR ASSISTING SURGICAL INTERVENTIONS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR REFUND

On or about June 9, 2003, Applicants timely filed a one month Response to Office Action (copies of PTO Office Action dated May 9, 2003 and the Response to Office Action are enclosed).

On August 31, 2003, a fee in the amount of \$410.00 for a two month extension of time was charged to Fish & Richardson's Deposit Account No. 06-1050.

Accordingly, the charge to Deposit Account No. 06-1050 was improper, as the response was timely filed and no fees were due. Applicants respectfully request that the overcharge amount be refunded to Fish & Richardson's Deposit Account No. 06-1050 as a credit.

OFFICE OF THE
REFUND DIVISION
SEP 16 5 AM 8-32
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Adjustment date: 10/01/2003 SDIRETA1
08/26/2003 RJCHNSDE 00000001 061050 09914640
01 FC:1252 410.00 CR

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date of Deposit: September 16, 2003
Signature:

Typed or Printed Name of Person Signing Certificate
Timothy A. French

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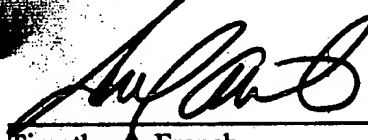
Applicant : Manfred Schmid et al.
Serial No. : 09/914,640
Filed : August 31, 2001
Page : 2 of 2

Attorney's Docket No.: 07508-033001

Respectfully submitted,

Date: _____

Sept 16, 2003



Timothy A. French
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APPLICATION NO.	FILING DATE	INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,640	02/14/2002		07508-053401	9652

7590 05/09/2003
Fish & Richardson
225 Franklin Street
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MAY 12 2003

FISH & RICHARDSON, P.C.
BOSTON OFFICE

EXAMINER

SHAH, DEVAANG

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 05/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED

MAY 13 2003

TIMOTHY A. FRENCH

Docketed By:	Reprk (1 mth)
Assigned To:	5/9/03
Due Date:	6/5/03
Expiry Date:	11/5/03
Initials:	6/5
Record:	

Docketed By:	ing Secretar
Due Date:	6/4/03
Deadline:	11-9-03
Initials:	juu



UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, DC 20231
www.uspto.gov

Paper No. 8

Notice of Non-Compliant Amendment (Voluntary Revised Practice)

The amendment filed 5-5-03 under the voluntary revised amendment practice guidelines¹, published in the Official Gazette on February 25, 2003 (*Amendments to a Patent Application Now Permitted*, 1267 Off. Gazette 106), does not fully comply with minimal requirements of the voluntary practice. For the amendment to be entered, it must either (1) comply with the guidelines of the voluntary revised amendment practice which practice invokes waivers of certain 37 CFR 1.121(a)-(d) requirements or (2) comply with current 37 CFR 1.121 requirements.

THE FOLLOWING ITEM(S) IN APPLICANT'S AMENDMENT CAUSES THE AMENDMENT TO BE NON-COMPLIANT WITH THE VOLUNTARY REVISED AMENDMENT PRACTICE.

- ☐ 1. A complete listing of all of the claims is not present in the amendment paper.
- ☐ 2. The listing of claims does not include the text of all claims currently under examination.
- ☐ 3. The claims of this amendment paper have not been presented in ascending numerical order.
- ☐ 4. Each claim has not been provided with a status identifier, and, as such, the individual status of each claim cannot be determined.
- ☒ 5. Other: The text of the new claims shouldn't be underlined.

LIE: Check one of the following boxes:

- ☐ **PRELIMINARY AMENDMENT:** Applicant is given ONE MONTH from the mail date of this letter to re-submit the amendment in compliance with either the guidelines of the revised amendment practice or current 37 CFR 1.121. Failure to comply with either the current 37 CFR 1.121 practice or with the voluntary practice will result in non-entry of the amendment and examination on the merits will commence without entry of the originally proposed preliminary amendment. This notice is not an action under 35 U.S.C. 132, and this ONE MONTH time limit is not extendable.
- ☒ **AMENDMENT AFTER NON-FINAL ACTION:** Since the above-mentioned reply appears to be a *bona fide* response, applicant is given a TIME PERIOD of ONE MONTH from the mailing of this notice within which to re-submit an amendment which complies with either the voluntary practice guidelines or current 37 CFR 1.121 in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).

Valerie Douglas
Team Leader

¹ For further explanation of the guidelines of the revised amendment format, please see the posted notice and sample amendment format at:
<http://www.uspto.gov/web/offices/pac/dapp/opla/propnotice/office/ver.pdf> and
<http://www.uspto.gov/web/offices/pac/dapp/opla/propnotice/formatrevamdtrac.pdf>

Attorney/Agent No. 07508-659001	Express Mail Label No.	Mailing Date June 9, 2001	For PTO Use Only <i>Do Not Mark in This Area</i>
Application No. 09/914,640	Filing Date August 31, 2001	Agency/Secretary Inlt TAF/BJC/erj	
Title of the Invention ACTIVE INSTRUMENT FOR DETERMINING A POSITION IN NAVIGATION AND FOR ASSISTING SURGICAL INTERVENTIONS			
Applicant Manfred Schmid et al.			
Enclosures Reply (Response to Notice of Non-Complaint Amendment) (13 pages and one additional sheet of drawing)			

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Manfred Schmid et al. ✓
Serial No. : 09/914,640 ✓
Filed : August 31, 2001 ✓
Title : ACTIVE INSTRUMENT FOR DETERMINING A POSITION IN NAVIGATION
SYSTEMS FOR ASSISTED SURGICAL INTERVENTIONS ✓

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY

In response to the Notice of Non-Complaint Amendment dated May 9, 2003, Applicants submit herewith a revised version of the Amendment filed April 29, 2003. In reply to the action mailed January 29, 2003, please amend the application as indicated on the following pages. Applicant asks that all claims be allowed in view of the amendment to the claims and remarks contained on the following sheets, a total of 13 pages.

Please apply any other charges or credits to Deposit Account No. 06-1050.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

June 9, 2003
Date of Deposit

Susan R. Jones
Signature

Susan R. Jones
Typed or Printed Name of Person Signing Certificate

Applicant : Manfred Schmid et al.
Serial No. : 09/914,640
Filed : August 31, 2001
Page : 2 f13

Attorney's Docket No.: 07508-033001

Respectfully submitted,

Date:

June 9, 2003

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In the specification:

Please amend the paragraph beginning at page 1, line 1 as follows:

Please insert the following Title into the specification. No new matter has been added.

**ACTIVE INSTRUMENT FOR DETERMINING A POSITION IN NAVIGATION
SYSTEMS FOR ASSISTING SURGICAL INTERVENTIONS**

Please insert the following Field of the Invention into the specification. No new matter has been added.

TECHNICAL FIELD

This invention relates to active instruments, and more particularly to solar-powered active instruments.

Please insert the following Background into the specification. No new matter has been added.

BACKGROUND

During surgical and examination procedures, the location of various instruments, such as probes and pointing devices, are superimposed onto a computer monitor that displays the relevant portion of the patient's body. A cable is used to connect the probe / pointing device to a navigation system that locates the device within the patient's body. Unfortunately, the use of a cable is inconvenient at best and complicates sterilization procedures.

Please insert the following Summary of Invention into the specification. No new matter has been added.

SUMMARY

According to an aspect of this invention, an untethered active instrument for determining a position in a navigation system that assists in surgical operations includes a power supply including one or more solar cells.

One or more of the following features may also be included. A buffer storage unit is interfaced with and buffers the power supply. The solar cells charge the buffer storage unit. The active instrument further includes one or more light sources, which are powered by the power

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supply and allow for the determination of the position of the active instrument. A wireless communication device (e.g., an infrared interface for data transfer) is powered by the power supply and allows for communication between the active instrument and the navigation system. One or more light sources are powered by the power supply and allow for the determination of the position of the active instrument.

Please insert the following Description of Drawings into the specification. No new matter has been added.

DESCRIPTION OF DRAWINGS

FIG. 1 is a plan view of an active instrument for determining a position in a navigation system.

Like reference symbols in the various drawings indicate like elements.

Please insert the following section title just prior to the existing specification. No new matter has been added.

DETAILED DESCRIPTION

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In the claims:

Please amend the claims as follows:

1. (cancelled)
2. (cancelled)
3. (cancelled)
4. (cancelled)
5. (new) An untethered, active instrument for determining a position in a navigation system that assists in surgical operations, comprising a power supply including one or more solar cells.
6. (new) The untethered, active instrument of claim 5 further comprising a buffer storage unit, which is interfaced with and buffers the power supply, wherein the one or more solar cells charge the buffer storage unit.
7. (new) The untethered, active instrument of claim 6 further comprising one or more light sources, which are powered by the power supply and allow for the determination of the position of the active instrument.
8. (new) The untethered, active instrument of claim 6 further comprising a wireless communication device that is powered by the power supply and allows for communication between the active instrument and the navigation system.
9. (new) The untethered, active instrument of claim 8 further comprising one or more light sources, which are powered by the power supply and allow for the determination of the position of the active instrument.
10. (new) The untethered, active instrument of claim 5 further comprising one or more light sources, which are powered by the power supply and allow for the determination of the position of the active instrument.

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11. (new) The untethered, active instrument of claim 10 further comprising a wireless communication device that is powered by the power supply and allows for communication between the active instrument and the navigation system.
12. (new) The untethered, active instrument of claim 5 further comprising a wireless communication device that is powered by the power supply and allows for communication between the active instrument and the navigation system.
13. (new) The untethered, active instrument of claim 12 wherein the wireless communication device is an infrared interface for data transfer.
14. (new) An untethered, active instrument for determining a position in a navigation system that assists in surgical operations, comprising:
 - a power supply including one or more solar cells;
 - one or more light sources, which are powered by the power supply and allow for the determination of the position of the active instrument; and
 - an infrared interface that is powered by the power supply and allows for data communication between the active instrument and the navigation system.
15. (new) The untethered, active instrument of claim 14 further comprising a buffer storage unit, which is interfaced with and buffers the power supply, wherein the one or more solar cells charge the buffer storage unit.
16. (new) An untethered, active instrument for determining a position in a navigation system that assists in surgical operations, comprising:
 - a power supply including one or more solar cells;
 - a buffer storage unit, which is interfaced with and buffers the power supply,
 - wherein the one or more solar cells charge the buffer storage unit;
 - one or more light sources, which are powered by the power supply and allow for the determination of the position of the active instrument; and

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an infrared interface that is powered by the power supply and allows for data communication between the active instrument and the navigation system.

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In the abstract:

Please replace the abstract with the following version.

The invention relates to an active instrument for determining a position in navigation systems which assist surgical interventions. The invention is characterised by a wireless transmission of energy. The energy for the power supply to the instrument can be supplied using wireless transmission elements, whereby at least one solar cell and a buffer storage unit are provided in the instrument. An untethered, active instrument that determines a position in a navigation system and assists in surgical operations includes supply having one or more solar cells.

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In the drawings:

Please substitute the attached FIG. 1 for the current figure present in the subject application.

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REMARKS

This Amendment is in response to the Notice of Non-Compliance dated May 9, 2003. Consideration thereof is respectfully requested.

The applicant appreciates the examiner's thorough examination of the subject application and requests reexamination and reconsideration of the subject application in view of the preceding amendments and the following remarks.

The examiner raises concerns with the drawing previously submitted in the subject application. In response to these concerns, applicant submits herewith a replacement FIG. 1. Applicant has amended FIG. 1 to include a reference to element 20 (See Applicant's specification, page 3, lines 36-37). No new matter has been added.

The examiner objects to the specification of the subject application. In response to these objections, applicant submits herewith a "Title", "Technical Field" portion, "Background" portion, "Summary" portion, and "Description of Drawings" portion. No new matter has been added.

The examiner rejects claim 4 under 37 CFR 1.74(c) as being in improper form because a multiple dependant claim cannot depend upon another multiple dependant claim. In response to this rejection, applicant has cancelled claims 1-4 and provided amended claims 5-16 that satisfy 37 CFR 1.74(c).

The examiner rejects claims 1-4 under 35 USC §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention. In response to this rejection, applicant has cancelled claims 1-4 and provided amended claims 5-16 that satisfy 35 USC §112.

The examiner rejects claims 1-4 under 35 USC §103(b) based on the combination of the teachings of Foley et al (U.S. Patent No. 6,021,343) and Hoborn et al (U.S. Patent No. 4,321,925).

The applicant claims (in, for example, new claim 5) "[an] untethered, active instrument for determining a position in a navigation system that assists in surgical operations, comprising a power supply including one or more solar cells". *Emphasis Added.*

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Applicant respectfully asserts that the combination of these two references do not teach the applicant's claimed *untethered* invention. Accordingly, applicant respectfully asserts that the combination of the teachings of Foley and Hoborn are not a proper basis for a 35 USC §103(b) rejection, as the combination does not teach each and every element of the applicant's claimed invention.

The use of active instruments during surgical procedures is becoming increasingly popular. As certain instruments (e.g., endoscopes, bronchoscopes, and biopsy needles) are used in an invasive manner, these devices must be properly sterilized in order to minimize the risk of infections. Accordingly, strict cleaning and sterilization procedures must be employed to minimize the chance of patient infection.

Complicating this cleaning and sterilization procedure is the fact that active devices are tethered to an external device. For example, an endoscope may include a plurality of optical positioning sensors or LED's at its base (i.e., the non-invasion portion of the scope) which are used in conjunction with a navigation system to determine the position of the endoscope within a patient's abdominal cavity. In order to power these sensors or LED's, the endoscope is tethered via a cable to the navigation system. This tether may also provide power to other devices on the endoscope, such as a surgical workspace illuminator. This tether presents multiple problems for the surgeon or technician using the device, as (1) the tether impedes freedom of movement, and (2) the tether complicates the sterilization procedure. This is especially true when you consider that a lot of these devices are sterilized in autoclaves.

The applicant's invention addresses these problems through the use of one or more solar cells (as opposed to a tether) that power the active device. This, in turn, reduces the complications associated with sterilizing the device and eliminates the mobility restriction imposed by the use of a tethered device.

As stated above, the examiner rejects the applicant's claimed invention based on the teachings of Foley in view of Hoborn. Applicant respectfully asserts that Hoborn is non-analogous art in that the Hoborn reference disclose the use of a solar cell to power a surgical glove perforation detector. What must be realized is that the device being powered in Hoborn is located in the shoe of the surgeon or technician performing the surgery. Accordingly, a person of ordinary skill in the art would not look toward the teaching of Hoborn to solve a problem

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concerning a device that must be sterilized. As previously and as stated above, the Hoborn device is located in a shoe, which includes exposed terminals that contact the floor of the operating theater and the insole of the shoe itself. Accordingly, the Hoborn device IS NOT intend or required to be sterilized, as (1) the device is not intended to contact the patient, and (2) any attempt to sterilize the device in Hoborn would most likely result in the device being destroyed. Additionally, any attempt to minimize the exposure of the Hoborn device to non-sterile environments (i.e., the floor) would require that the Hoborn device be insulated and isolated from the floor. As clearly realizable and understandable from the Hoborn reference, this would prevent the Hoborn device from working properly. Additionally, as the Hoborn device is clearly not intended to be sterilized, the Hoborn reference actually teaches away from the applicant's easily-sterilizable claimed invention, which claims a "[an] untethered, active instrument...".

Additionally, the Foley reference clearly teaches the use of a tethered system. (See *Foley, Fig. 1, item 161*). Further, the Hoborn reference also *inherently* teaches a system that is tethered. Specifically, the Hoborn reference concerns a glove perforation detection system in which the conductivity between a pair of terminals (See *Hoborn, fig. 5, items A & B*) is monitored. These terminals create an electrical path in which, in the event of a glove perforation, a current flows between the pair of terminals via a conductive path comprising the body of the surgeon / technician, the patient, the operating table, and the floor of the operating theater. Therefore, in the event of a perforation, a current will flow from the hand of the surgeon / technician, through the glove perforation, and into the body of the patient, thus completing the conductive path and being indicative of a glove failure. Therefore, the only way that the Hoborn system works is if the surgeon / technician is touching the patient. Accordingly, if the surgeon / technician is not touching the patient, the conductive path will never be completed, even in the event of a glove failure.

Accordingly, for the Hoborn system to function properly, the surgeon / technician is "tethered" to the patient, wherein the "tether" is the arm of the surgeon / technician and, therefore, failure by the surgeon to maintain contact with the patient renders the Hoborn device inoperable for its intended purpose, namely indicating the perforation of a surgical glove.

Accordingly, the applicant respectfully asserts that the combination of the Foley and Hoborn references do not teach each and every element of the applicant's claimed invention,

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namely an "untethered, active instrument". Therefore, applicant respectfully asserts that independent claims 5, 14, and 16 are patentable over the combination of the teachings of Foley and Hoborn. Additionally, applicant respectfully asserts that claims 6-13, and 15 are also allowable, as they depend either directly or indirectly upon an allowable base claim.

Applicant respectfully asserts that all claims are in condition for allowance and applicant respectfully asks that all claims be allowed.

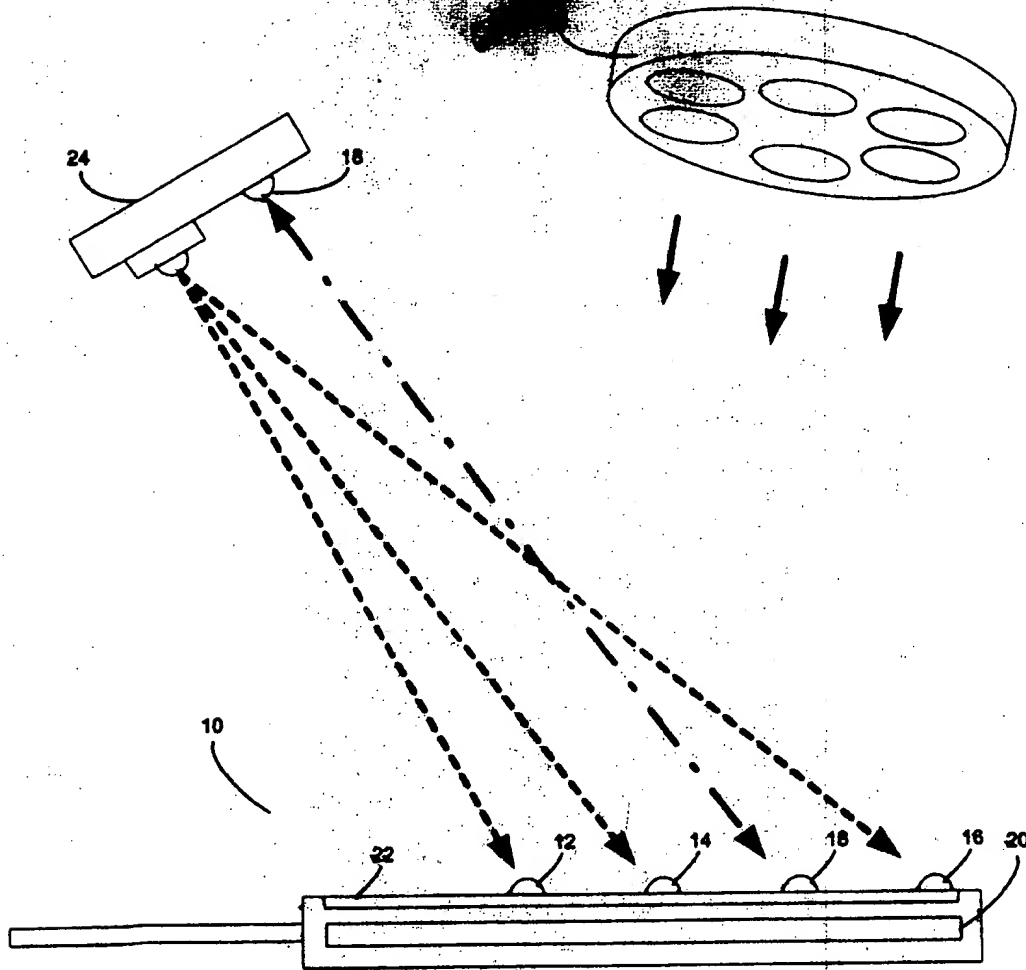


FIG. 1

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above.

If the rights held by the above identified small business concern are not exclusive, each individual, concern, or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 C.F.R. § 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 C.F.R. § 1.9(d), or a nonprofit organization under 37 C.F.R. § 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern, or organization having rights to the invention averring to their status as small entities (37 C.F.R. § 1.27).

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which the status as a small entity is no longer appropriate (37 C.F.R. § 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Signature: _____

Name: _____

S. Ted DiNoVo

Title: _____

President

Date: _____

10-5-00